Remarks

Continued Examination of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 10-12, 14, 15, and 79 are cancelled without prejudice to or disclaimer of the subject matter therein. Applicants have cancelled these claims solely to advance prosecution and not in acquiescence to Examiners objections or rejections. Applicants reserve the right to prosecute cancelled claims in the future.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

The Enablement Rejection

The Examiner rejected claims 71-77 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Applicants respectfully traverse this rejection.

The Examiner stated that

> one of skill in the art would not use a variant of SEQ ID NO:1 in a hybridization method for detecting SEQ ID NO:1 as indicative of stage-specific breast cancer as the hybridization would preferentially detect the variant of SEQ ID NO:1, not SEQ ID NO:1.

Paper No. 22, page 2.

The Examiner further stated that the specification is not enabling because "one of skill in the art would not use a variant polypeptide to generate antibodies that would bind SEQ ID NO:2, as the variant polypeptide would contain epitopes that would produce antibodies which did not bind SEQ ID NO:2." Paper No. 22, page 3.

Whether or not the ordinary artisan would preferentially use polynucleotides which are 95% identical to SEQ ID NO:1 as an indicator of breast cancer or variant polynucleotides to generate antibodies to bind the polypeptide of SEQ ID NO:2 is irrelevant to an enablement analysis. What is relevant is whether one of ordinary skill in the art *could* use the polynucleotides of the invention, not whether they *would* choose to use them over a polynucleotide which is 100% identical to SEQ ID NO:1.

Polynucleotides that are at least 95% identical to SEQ ID NO:1 are useful to detect SEQ ID NO:1 and, as such, the presence of breast cancer. *See*, Specification page 9, lines 27-35 and page 10, lines 1-7. A variant of SEQ ID NO:1 that is 95% identical to SEQ ID NO:1 will hybridize due to the level of identity between the variant and SEQ ID NO:1. Therefore, one of skill in the art *could* use a variant of SEQ ID NO:1 in a hybridization method for detecting SEQ ID NO:1 as indicative of stage-specific breast cancer.

Even assuming *arguendo* that a variant of SEQ ID NO:1 is present and the polynucleotide which is 95% identical to SEQ ID NO:1 would preferentially hybridize that variant over SEQ ID NO:1, some 95% identical polynucleotide will still hybridize with SEQ ID NO:1 given the 95% identity between them. This occurs even in the presence of a variant polynucleotide competing with SEQ ID NO:1 for hybridization.

Variant polynucleotides may be used to generate antibodies to bind the polypeptide of SEQ ID NO:2 and detect SEQ ID NO:2. *See*, Specification page 18, lines 3-35 and page 19 lines 1-22. The Examiner herself stated that the specification teaches "polynucleotides comprising nucleic acids which encode fragments of SEQ ID NO:2 from amino acids 94-107 and amino acids 120-127 as antigenic regions of the BCSG1 protein." Paper No. 19, page 3. The specification also points out that certain amino acid substitutions are less likely to effect

protein function. *See* Specification page 14, lines 3-16 (offering guidance concerning phenotypically silent amino acid substitutions). With this guidance, one of ordinary skill in the art could readily generate variant polypeptides with epitopes that would produce antibodies which bind SEQ ID NO:2. Therefore one of ordinary skill in the art *could* use variant polypeptides to generate antibodies that would bind SEQ ID NO:2. Even assuming *arguendo* that some of these polypeptide may produce other antibodies which do not bind SEQ ID NO:2, they will still produce antibodies which are specific for SEQ ID NO:2.

In fact, one of ordinary skill upon reading the specification may choose polynucleotides which are 95% identical to SEQ ID NO:1 as an indicator of breast cancer or variant polynucleotides used to generate antibodies to bind the polypeptide of SEQ ID NO:2 over polynucleotides that are 100% identical to SEQ ID NO:1 for a number of reasons, such as ease of production, stability or availability of materials.

Moreover, optimality is not required for enablement. *See Atlas Powder Co v. E.I Du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ409, 414 (Fed. Cir. 1984); *see also, In re Cook*, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

Applicants assert that the claims are fully enabled, as one of ordinary skill in the art would know how to make and use the polynucleotides of the invention. Accordingly, withdrawal of this rejection is respectfully requested.

Best Mode

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all currently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

Claims 10-12, 14, 15, and 79 were cancelled.